



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/827,297

04/20/2004

Michael B. Zemel

31894-199298

2570

26694

7590

08/08/2008

VENABLE LLP

P.O. BOX 34385

WASHINGTON, DC 20043-9998

EXAMINER

FISHER, ABIGAIL L

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

08/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/827,297	Applicant(s) ZEMEL ET AL.	
	Examiner ABIGAIL FISHER	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/7/07, 6/20/07, 5/4/07, 10/18/06, 8/4/05, 5/27/05,</u> | 6) <input type="checkbox"/> Other: ____. |
| <u>4/20/04.</u> | |

DETAILED ACTION

Claims 1-28 are pending.

Information Disclosure Statement

The information disclosure statement April 20 2004, specifically item A12, fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered. This document is a videotape, and it is unclear what content of this videotape is relevant as the examiner could not find any synopsis of the videotape.

The information disclosure statements (IDS) submitted on 5/27/05, 8/4/05, 10/18/06, 5/4/07, 6/20/07 and 12/07/07 were considered by the examiner.

Specification

The examiner acknowledges the amendment to the specification filed on April 20 2004. This amendment changed the information in the table under item 4. Dairy consumption was changed from 1346 ± 113 to 102.9 ± 3.6 . The applicant indicated that this was an obvious typographical mistake and that a published article to the instant inventors (FASEB Journal, 2000, 14(9), pp. 1132-1138 which was submitted on PTO Form 1449) shows the correct table. The examiner agrees and therefore the amendment to the specification has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are vague and indefinite. The claims contain the phrase “at least about”. This phrase renders the claims indefinite as it is unclear what constitutes the lower limit of the claimed amount. For example in claim 2 is the amount of dietary calcium at least 1000 mg/day or is it about 1000 mg/day?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7-10, 12-23 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Science Daily (1999, cited on PTO Form 1449) in view of Summerbell et al. (BMJ, cited on PTO Form 1449).

Applicant Claims

Applicant claims a method of regulating the body weight of an individual comprising the steps of (a) providing the individual with information disclosing that consuming dietary calcium and/or dairy products is associated with one or more health effects selected from loss and/or reduced gain of weight and/or fat, and/or metabolic consumption of adipose tissue, and (b) providing the individual with a dietary plan for consuming products containing an effective amount of dietary calcium and/or dairy products sufficient to induce the one or more health effects.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Science Daily is directed to a study of the effect of calcium on weight gain. It is disclosed that when overall calorie consumption is account for, calcium not only helps to keep weight in check but can be associated specifically with decreases in body fat (paragraph 1). It is disclosed that when women of the study consumed a diet of 1900 calories or less, those who consumed an average of 1000 mg of calcium per day showed an overall decrease in body weight (paragraph 4 and 5) especially when compared to women those consumed less than 1900 calories but averaged less than 780 mg of calcium per day. The women who averaged less than 780 mg of calcium actually gained body fat mass over the same period (paragraph 4). Women who received their calcium from dairy sources such as milk, yogurt and cheese showed more benefits than those who primarily used non-dairy sources such as vegetables, nuts, beans, and calcium supplements (paragraph 8). It is disclosed that women who consume calcium from dairy products or who consume at least 1000 mg per day of calcium may reap the most benefit (abstract, second paragraph).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Science Daily does not specify providing a dietary plan to an individual but does indicates parameters one must follow to lose weight. Science Daily does not disclose preparing an analysis of the individuals' dietary intake of calcium and/or dairy or monitoring calcium intake. Science Daily does not specify determining the height or weight or BMI of the individual. However, this deficiency relating to a dietary plan is cured by Summerbell et al.

Summerbell et al. is directed to weight reducing diets. The diets of the trial were directed to reducing weight in patents with a body mass index (BMI) greater than 27 (abstract). Three diets were administered. Diet 1 was a control. Diet 2 was a milk only diet. Diet three was a milk plus diet, which consisted of milk with the addition of unlimited amount of a single food (page 1488, interventions). All the patients had their weight and height measured and were given appoints to return to the clinic every four weeks for 16 weeks. On the first visit a medical history was taken. A nurse then gave the patient dietary advice and told them to follow one of the three diets (these diets were assigned to each patient). Upon subsequent visits, the nurses reviewed the food records and provided advice about the diet to the patient (page 1487-1488, last paragraph of the Recruitment and randomization section). After the study was complete, a statistical analysis was performed of the results of the patients' BMI and weight loss (page 1488, statistical analysis and table 1). It is disclosed that in the milk only diet patients achieved the highest overall mean weight loss (page 1489, first paragraph).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art to combine the teachings of Science Daily and Summerbell et al. and utilize a dietary plan. One of ordinary skill in the art would have been motivated to provide an individual with a dietary plan as Science Daily teaches specific amounts of calories as well as specific amounts of calcium to be consumed daily. Summerbell et al. indicates a procedure for clinicians to administer dietary information regarding calcium diets to a patient. Therefore it would

Art Unit: 1616

have been obvious to one of ordinary skill in the art to formulate the teachings Science Daily into a dietary plan for clinicians to utilize for patients on calcium diets.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Science Daily and Summerbell et al. and utilize an analysis of the individuals' intake of calcium and/or dairy and monitor their calcium intake. One of ordinary skill in the art would have been motivated to perform this type of analysis because Science Daily discloses particular amounts of calcium that are needed to weight loss and Summerbell et al. indicate performing analysis of the performance of participants of the study to determine effectiveness of their diet. One of ordinary skill in the art would have been motivated to perform an analysis of the individuals' intake of calcium and continue to monitor their intake to ensure that they were meeting the requirements taught by Science Daily for effective weight loss.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Science Daily and Summerbell et al. and take an individuals height and weight before having them supplement their diet with calcium. One of ordinary skill in the art would have been motivated to take a height and weight measurement as Summerbell et al. teach taking an individuals height and weight to have a starting point for comparison as well as utilizing this information for determination of a BMI. One of ordinary skill in the art would have been motivated to take a height and weight measurement and the subsequent BMI of an individual to determine a starting point in order to monitor a patient's weight loss.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 6, 11, 24 and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Science Daily in view of Summerbell et al. and in further view of Brown et al. (US Patent No. 5879163).

Applicant Claims

Applicant claims that information is obtained by having the individual answer questions over the internet, and the information is analyzed by a computer after input of the data by the individual, and the information is compared to a database containing the nutritive values of the foods, and the nutritional composition of the diet of the individual is provided, including the amount of calcium consumed, and further comprising providing recommendations regarding increases in the amount of calcium consumed by the individual if the amount of dietary calcium consumed is suboptimal.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Science Daily and Summerbell et al. are set forth above. Specifically, Science Daily teaches that women of the study consumed a diet of 1900 calories or less, those who consumed an average of 1000 mg of calcium per day showed an overall decrease in body weight especially when compared to women those

Art Unit: 1616

consumed less than 1900 calories but averaged less than 780 mg of calcium per day. The women who averaged less than 780 mg of calcium actually gained body fat mass over the same period. Summerbell et al. is directed to a study with various calcium rich diets. A particular diet plan was chosen for each individual and the individuals' height, weight, and BMI were recorded before, during, and after completion of the study.

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Science Daily and Summerbell et al. do not specify utilizing a computer or the internet for obtaining patient information or analyzing the information. However, this deficiency is cured by Brown et al.

Brown et al. is directed to automated system which includes a questionnaire to provide health education to an individual (abstract). It is taught that due to the disadvantages of private analysis and education, attempts have been made to implement computer-automated health education systems that are available to the general public (column 2, lines 52-55). The automated system of the invention is connected to a remote terminal via a communication network (column 4, lines 57-58). The systems includes a profile generator for receiving via the communication network questionnaire answers entered by an individual and for generating from the questionnaire answers a motivational diver profile (columns 4-5, lines 65-67 and 1-2). In a preferred embodiment the communication network is a public network such as the Internet (column 6, lines 49-50). The questionnaire generator is capable of generating an interactive interview form. Additionally included is a registration form which includes name, language and current health condition of the individual (columns 6-7, lines 60-67

Art Unit: 1616

and 1-5). It is taught that the questionnaire can be tailored to a particular health condition of an individual (column 7, lines 11-12). First pattern and health histories are taken then a second category for determining a motivation driver is conducted (column 7, lines 19-40). The operation of the preferred embodiment is a system which provides customized health education to an individual to induce a modification in a health-related behavior of an individual. It is taught that the system can be effective for customizing health education to induce behavior modification in individuals suffering from any health-related condition (column 12, lines 14-17).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art to combine the teachings of Science Daily, Summerbell et al., and Brown et al. and utilize a computer system to educate an individual about calcium and its use in causing weight loss. One of ordinary skill in the art would have been motivated to utilize a computer system because Science Daily teach that calcium is effective in preventing weight loss and Summerbell et al. teach administration of a diet plan of a calcium diet to individuals upon appointments at a clinic or hospital. Brown et al. teach that due to the disadvantages of private analysis and education, attempts have been made to implement computer-automated health education systems that are available to the general public. Therefore, one of ordinary skill in the art would have been motivated to combine the teachings Science Daily, Summerbell et al., and Brown et al. to educate individuals who are suffering from the health-related condition of obesity that calcium can be utilized to cause weight loss. One of ordinary skill would have been motivated to

Art Unit: 1616

utilize the system of Brown et al. because it can be tailored to a specific health-related condition and individual. Since Science Daily teaches that the amount of calcium consumed each day is important, one of ordinary skill would have been motivated to utilize the system of Brown et al. to analyze an individual's current health condition and make the appropriate adjustments to ensure that they are consuming the appropriate amount of calcium to cause weight loss.

Regarding the administration of at least 57 servings of dairy per month the amount of calcium instant claimed and that of Science Daily is the same (at least 1000 mg/day). Therefore, depending on the source of the calcium it would have been obvious to one of ordinary skill in the art to determine the appropriate number of servings to consume in order to reach the required daily amount of at least 1000 mg/day.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

Art Unit: 1616

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 7-10, 12-23 and 25-26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 10-15 of copending Application No. 10827296. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant application claims a method of regulating the body weight of an individual comprising the steps of (a) providing the individual with information disclosing that consuming dietary calcium and/or dairy products is associated with one or more health effects selected from loss and/or reduced gain of weight and/or fat, and/or metabolic consumption of adipose tissue, and (b) providing the individual with a dietary plan for consuming products containing an effective amount of dietary calcium and/or dairy products sufficient to induce the one or more health effects.

Copending '296 claims a method of avoid health problems in an individual at risk thereof due to excess body weight and/or an excess of body fat, the individual suffering from at least Grade I obesity, comprising in combination during a period of time: administer to the individual one or more servings of a dairy product comprising a sufficient amount of dietary calcium of at least about 773 mg per day to induce weight loss, reduce weight gain, and/or increase the metabolic consumption of adipose tissue in the individual, and maintaining the individual on a restricted caloric diet below ad lib in

Art Unit: 1616

a range of about 200 kcal to about 2500 kcal per day, wherein the individual is a women and the one or more servings is at least about 57 servings of dairy per month.

Copending '296 does not claim providing an individual with information disclosing that consuming dietary calcium is associated with one or more health effects. However, in order to practice the invention of copending '296, one would necessarily have to be provided with the information that consuming calcium products is associated with one or more health effects as the method of copending '296 is directed to administering calcium to avoid health problems. One of ordinary skill would have to have been informed of calcium's benefit in order to practice the method of copending '296. Therefore, the scopes of the copending '296 claims and the instant application overlap and thus they are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-5, 7-10, 12-23 and 25-26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 10-17 and 19-22 of copending Application No. 10827307. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant claims are set forth above.

Copending '307 claims a method of including weight loss and/or increasing the metabolic consumption of tissue in an individual suffering from obesity, wherein obesity

Art Unit: 1616

is selected from the group consisting of Grade I, Grade II, and Grade III obesity, wherein the method comprising in combination during a period of time administering to the obese individual one or more servings of one more calcium calcium-containing products where the one or more servings comprise an amount of dietary calcium of at least about 773 mg per day, sufficient to include with loss, and/or increase the metabolic consumption of adipose tissues, and restricting said obese individual to a caloric intake below ad lib in a range of about 200 kcal to about 2500 kcal per day where in the individual is a women and the one or more servings comprise at least about 57 servings of dairy per month.

Copending '307 does not claim providing an individual with information disclosing that consuming dietary calcium is associated with one or more heath effects. However, in order to practice the invention of copending '307, one would necessarily have to be provided with the information that consuming calcium products is associated with one or more heath effects as the method of copending '307 is directed to administering calcium to avoid health problems. One of ordinary skill would have to have been informed of calcium's benefit in order to practice the method of copending '307. Therefore, the scopes of the copending '307 claims and the instant application overlap and thus they are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Mina Haghighatian/
Primary Examiner, Art Unit 1616